

Translation

PATENT COOPERATION TREATY

PCT/JP2003/010461



PCT

524970

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | |
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| Applicant's or agent's file reference SAP-702-PCT | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/JP2003/010461 | International filing date (day/month/year) 19 August 2003 (19.08.2003) | Priority date (day/month/year) 20 August 2002 (20.08.2002) |
| International Patent Classification (IPC) or national classification and IPC C07K 14/47, 14/42, C12P 21/02, C12Q 1/02, G01N 33/48 | | |
| Applicant SUMMIT GLYCORESEARCH CORPORATION | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) 1 DISC, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☒ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

| | |
|---|--|
| Date of submission of the demand 04 February 2004 (04.02.2004) | Date of completion of this report 01 June 2004 (01.06.2004) |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/10461

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------|-----|
| Novelty (N) | Claims | 1-16 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-16 | NO |
| Industrial applicability (IA) | Claims | 1-16 | YES |
| | Claims | | NO |

2. Citations and explanations

Document 1: M. Yim et al., "Mutated plant lectin library useful to identify different cells", Proc. Natl. Acad. Sci. USA, 2001, Vol. 98, No. 5, pp. 2222-5; especially p. 2224

Document 2: A. Imberty et al., "An unusual carbohydrate binding site revealed by the structures of two *Maackia amurensis* lectins complexed with sialic acid-containing oligosaccharides", J. Biol. Chem., 2000, Vol. 275, No. 23, pp. 17541-8; especially p. 17541, right column. lines 24-38

Document 3: F. P. Schena et al., "Increased serum levels of IgA1-IgG immune complexes and anti-F(ab')₂ antibodies in patients with primary IgA nephropathy", Clin. Exp. Immunol., 1989, Vol. 77, No. 1, pp. 15-20

Document 4: WO 95/15979 A1 (Neorx Corp.), 15 June 1995 & EP 733066 A1 & JP 9-506594 A & US 5976535 A & EP 1346730 A1

Claims 1-15

Document 1 discloses formation of a lectin library containing a plurality of lectins derived from the legume

lectin MAH, and use of said library to identify different sugar chains on red blood cells and to fractionate cells.

Document 2 discloses the fact that the lectin MAH identifies O-bound sugar chains.

Document 3 discloses the use of lectins to distinguish IgA sugar chains.

In this connection, these documents do not mention specific selection of suitable lectins based on their affinity for cells, and construction of a library which is more effective for the purpose thereof; however, when constructing libraries for a purpose in general, and not only lectin libraries, selection of members chosen in accordance with the purpose thereof is conventionally an important factor in constituting the library (see, if necessary, JP 8-500483 A and JP 2002-181826 A).

Therefore, given documents 1 to 3, a person skilled in the art could easily conceive of using a lectin library selected in accordance with the purpose thereof to identify different sugar chains and separate cell fractions in different cells populations, and of selecting for this purpose lectins such as lectins which recognize O-bound sugar chains and/or lectins which distinguish IgA sugar chains.

Moreover, constitution of the claims in the present application does not appear to present any special difficulty, since these do not specify the lectins but only specify cell fractions to be isolated.

Presentation of the resulting lectin library in the form of a lectin chip or lectin sensor are also suitable options available to a person skilled in the art.

Therefore, the inventions set forth in claims 1 to 15 could be deduced easily by a person skilled in the art from the disclosures in documents 1 to 3.

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Claim 16

Document 4 discloses a method of purification using plasmapheresis and a column, and presents lectin/-carbohydrate as an example of a ligand pair demonstrating selective binding of high affinity.

In this connection, a person skilled in the art could easily conceive of plasmapheresis using a lectin library obtained as described above.

Therefore, the invention set forth in claim 16 could be deduced easily by a person skilled in the art from the disclosures in documents 1 to 4.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

| Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|-------------------------------|--------------------------------------|---------------------------------|---|
| WO 02/66633 A1 [PX] | 29 August 2002 (29.08.2002) | 20 February 2002 (20.02.2002) | 20 February 2001 (20.02.2001) |

2. Non-written disclosures (Rule 70.9)

| Kind of non-written disclosure | Date of non-written disclosure (day/month/year) | Date of written disclosure referring to non-written disclosure (day/month/year) |
|--------------------------------|--|---|
|--------------------------------|--|---|